

REMARKS

The Applicant appreciates the thorough review of the Application by the Examiner and the indication of allowable subject matter. Allowance of all claims as amended is respectfully requested. By this Amendment, Claim 1 has been amended to clarify that the electrical connection means are part of the blister label. No new matter has been added by the amendment. No new issues are raised by the amendment. Claims 13 - 21 have been withdrawn and Claims 1 - 21 remain pending in the application.

Claims 1 - 4, 7, 9, and 12 are patentable under 35 U.S.C. 102(b) over Parkhurst et al. (U.S. 5,412,372).

Parkhurst is a portable medication dispenser for monitoring dispensing times. A blister package and separate disposable sensor sheet are loaded into a housing with electronics and an alarm. The sensor sheet has electrical sensing regions corresponding to each compartment of the blister package and is scanned multiple times each second by a control circuit. When a medication is ejected through the blister package and sensor sheet, a temporary break in the circuit is detected by the monitoring control circuit and registered as a dose dispensing.

(Abstract, Col. 3, lines 30-52, Figures)

For an invention to be anticipated, it must be demonstrated that each and every element of the claimed invention is present in the "four corners" of a single prior art, either expressly described therein or under the principle of inherency. Lewmar Marine Inc. v Barient Inc., 3 USPQ2d 1766, 1767-1768 (Fed. Cir. 1987) (emphasis added). The absence from a prior art reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible, Inc., 230 USPQ 81, 84 (Fed. Cir. 1986).

Although Applicant disagrees with the rejections of record, Claim 1 has been amended to more clearly distinguish from the cited prior art. Claim 1 as amended is distinguished from Parkhurst at least in that it teaches that the blister label comprises for each drug dose an electrical connection means such that when the label is ruptured the electrical connection means will break, wherein each electrical connection means is connected in either end to a first and second lead in parallel electrical connection, and that at least two contact islands are provided at terminal ends of the first and second lead, adjacent an edge of the blister label. Parkhurst does not teach or suggest any of these features.

The Examiner describes element 143 of Parkhurst as a blister label and element 156 as electrical connection means. However, there is no element 143 in Parkhurst. Element 148 of Parkhurst is a sensor sheet, which is placed on the back of a blister package 30. In the present invention, the blister label is defined as the layer that closes the depressions in the flexible foil that hold the medication. (Page 3, lines 28-33) Elements 154 and 156 of Parkhurst, as shown in figures 7 and 7A, are conductive, metallic foil circuit layers between non-conductive outer layers 150, 152 of the sensor sheet 148. The sensor sheet 148 of Parkhurst is separate from the blister package and disposable and is used with a standard blister package.

Thus, sensor sheet 148 of Parkhurst cannot be considered comparable to the blister label of the present invention. It does not seal off the depressions in the blister package. It is the backing layer of the blister package in Parkhurst that performs that function. Therefore, the metallic foil circuit layers of Parkhurst, which are inside the sensor sheet, are not part of the blister label. Parkhurst therefore does not teach or suggest that the blister label comprises for each drug dose an electrical connection means such that when the label is ruptured the electrical

connection means will break. The metallic foil circuit layers of Parkhurst are part of the sensor sheet and are momentarily separated when the medication passes through the sensor sheet.

Furthermore, Parkhurst does not teach or suggest electrical connection means where said means is extending across each rupturable zone, wherein each electrical connection means is connected in either end to a first and second lead in parallel electrical connection. The Examiner argues that Parkhurst teaches "each electrical connection [156] is connected at either end to first and second leads 154, 180 in parallel connection." Applicant cannot agree.

Element 156 is a metallic foil circuit layer inside sensor sheet 148 and is represented by a dashed line in Figure 6. Element 154 is a second metallic foil circuit layer in sensor sheet 148 that overlaps with element 156 at each compartment of a blister package as shown in Figures 6 and 7. Element 180 is an elastomeric connector running the length of the sensor sheet as shown in Figure 6 that connects the sensor sheet to the rest of the detection circuitry. Element 156 does touch element 180, as shown in Figure 6, and element 154, as shown in Figures 6 and 7. However, element 156 is not connected at either end to first and second leads in parallel electrical connection. It is not in a parallel electrical connection and it is not connected at either end.

Parkhurst also does not teach or suggest at least two contact islands are provided at terminal ends of the first and second lead, adjacent an edge of the blister label. The Examiner argues that Parkhurst teaches "two contact islands 154, 180 adjacent an end of the blister label." Applicant cannot agree.

The Examiner is arguing that the same elements in Parkhurst constitute both the first and second leads and the two contact islands at the terminal ends of the first and second leads. This is improper, as it essentially reads out an element of the claim. In any case, element 180 is not a

contact island at the terminal end of element 180. Furthermore, it is not clear what the terminal ends of element 154 would be. Parkhurst does not teach or suggest contact islands at all.

Parkhurst fails to teach or suggest each and every element of Claim 1. Claims 1 - 4, 7, 9, and 12 depend from independent and patentable Claim 1 and share its patentable limitations and add further patentable features. Examples are given below.

Claim 2 adds a second set of contact islands provided in the opposite end to the first contact islands of said first and second leads, whereby a redundancy measurement may be conducted. Parkhurst does not teach or suggest this limitation. The Examiner argues that foil circuit layer 154 and elastomeric connector 181 constitute this second set of contact islands. Foil circuit layer 154 cannot be a lead and a first set of contact islands at terminal ends of a lead and a second set of contact islands opposite the first set of contact islands. Elastomeric connector 181 is not a contact island.

Claim 3 adds a reference resistor is integral with one of the first or second leads. Parkhurst does not teach or suggest this limitation. The lines cited to by the Examiner do not read on this limitation and have to do with alternative embodiments other than those having layers 154 and 156.

Claim 4 adds a second set of electrical connection means corresponding to a second row of drug doses arranged on said blister label is provided, and that said second set of electrical connection means are connected in parallel in a first end of said connection means to the first or second lead and in a second end of said electrical connection means to a third lead, and that said third lead is provided with at least a contact island adjacent the contact islands of the first and second leads, adjacent an edge of the blister label. Parkhurst does not teach or suggest this limitation. The Examiner argues that Parkhurst teaches "second set of connection means...

connected in the same manner as the right side connection means," which is not what the claim requires.

Claim 7 adds that the label is partly perforated along the outline of each rupturable zone. Parkhurst does not teach or suggest this limitation. The lines cited to by the Examiner do not refer to a blister label, but to a single metallic foil layer that, in one embodiment, could replace elements 154 and 156.

Claim 9 adds that all leads share the same contact islands. Parkhurst does not teach or suggest this limitation. The Examiner cites to Figure 6 but gives no explanation.

Claim 12 adds that data relating to any one or more of the following: drug user, drug type, drug identification, drug manufacturer, sequence of dispensing each dose, prescribing doctor or hospital may be stored on the label. Parkhurst does not teach or suggest this limitation. The lines cited to by the Examiner refer to the separate device and not to a blister label.

For at least the above reasons, Claims 1 - 4, 7, 9, and 12 are patentable under 35 U.S.C. 102(b) over Parkhurst. The rejection is therefore improper and should be withdrawn.

Claim 11 is patentable under 35 U.S.C. 103(a) over Parkhurst et al.

Claim 11 depends from independent and patentable Claim 1 and adds further patentable limitations. The Examiner cites no art in concluding that the elements of Claim 11 would be obvious. The Examiner argues that "The placement of the contact islands on the label would be an obvious matter of design for one of ordinary skill in the art. An asymmetrical arrangement thereof would be an obvious means for ensuring the alignment of the label within the device in the correct position." Applicant cannot agree and traverses the Examiner's holding of obviousness without citing to art.

Such holdings are known as taking "Official Notice" under MPEP § 2144.03. MPEP § 2144.03(A) states that "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." (emphasis added) Providing that at least two contact islands are arranged asymmetrically on the label is not capable of instant and unquestionable demonstration as being well-known. This is demonstrated by the complete lack of evidence of such a limitation in the record.

For at least the above reasons, the rejection of Claim 11 under 35 U.S.C. 103(a) over Parkhurst is improper and should be withdrawn.

The examiner refers to Parkhurst as providing a solution comparable to the solution proposed in the characterising portion of claim 1 of the present application. However, from Parkhurst, and in particular from the passages cited by the examiner, the differences between the device and blister package according to Parkhurst and the invention defined in claim 1 are evident:

- Col. 7, line 60 to Col. 8, line 7 recites general considerations for these types of devices without giving any structural information or details;
- Col. 8, lines 22-24 recites the possible electrical parameters which may be used for measurement and, thereby, (implicitly) indicates the types of sensors and measuring circuit which shall be used;
- Col. 9, lines 7-27 describes a package construction where the package comprises a medication panel (114), and a disposable sensor sheet (148) where the sheet (148) is made up of several layers by lamination of conductive and non-conductive layers, and the backing layer

of the medications' own package. Consequently at least four layers are arranged through which the medication has to be forced. Furthermore, the conductive layer(s?) in the sensing regions (it is assumed that these regions correspond to the blister formations on the medication package) comprises overlapping metallic foil layers. Although the construction is not clearly described, it may be deducted that at least four layers separate the medication in the blister from the outside of the package. Furthermore, this construction apparently has the inconvenience as described in the 5 lines following the quotation, namely that it is necessary to scan the circuitry quite often (four times per second) as the many layers may snap back and close the circuit again after the passage of the dispensed medication.

- Parkhurst does not have a single embodiment where attempts to limit the amount of contact points are described or illustrated.

- Col. 10, lines 36-39 recites the provision of a redundant elastomeric connection (181). How this elastomeric connection helps in ensuring good electrical connections and assists in mechanically securing the package in place (in the device) is unclear.

- Col. 11, lines 41 to 49 does not add anything which was not already introduced by the citations. Furthermore the passage is concerned with an at least four layer construction and a multitude of contact points

- Col. 13, lines 54 to 68, appears to be the only passage which may be considered relevant in view of the present invention. It should, however, be noted that the very general mentioning of the different types of circuitry is to be seen in connection with the overall construction of the devices according to Parkhurst. Also a number of drawbacks are described: line 60: "although they may require more complicated detection circuitry...", line 68: "Changes in a series or parallel connected array of sensor elements would signal how many but not which articles which

had been dispensed...". The skilled person would see these drawbacks or further complications in Parkhurst as teaching away and would disregard the teachings of Parkhurst in solving the problem posed above.

In conclusion, the passages from Parkhurst are all relating to a construction which is clearly different from the construction of the present invention. Parkhurst comprises, as far as may be deducted from the disclosure, at least four layers, whereas the label of the present invention comprises the backing foil and the electrical leads extending across the rupturable zones.

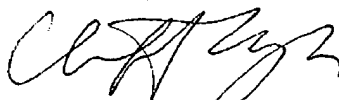
The circuitry of Parkhurst, is also not clearly defined in relation to the layered construction. The skilled person is, furthermore, thought that when using the construction according to Parkhurst, the device must comprise certain features, i.e. be able to test the circuitry four times per second (col. 9, lines 27-31), and that a "more complicated detection circuitry" (Col. 13, line 60) is required.

These features all teach the skilled person to look elsewhere for a possible solution to the problem deriving from the inventive features of the present invention. As such features are not suggested or even hinted at, as solutions to comparable problems in the available prior art documents, it is submitted that the independent claim 1 is both to be considered novel and is not obvious.

CONCLUSION

Reconsideration and allowance of all claims are respectfully requested.

Respectfully,



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